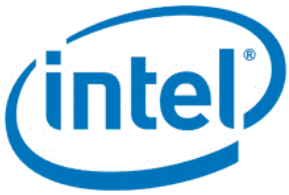

October 24, 2016

Mr. Steven Posnack
Director Office of Standards and Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20024Re: Comments on the Draft 2017 Interoperability Standards Advisory

Dear Mr. Posnack:

For a decade, Intel has worked with many in the industry and government agencies to create the Continua Design Guidelines which are based on specific standards now adopted by the ITU and other government agencies worldwide. We are submitting these comments to invite the US to participate in a growing acknowledgment of the value that this suite of standards brings to personal connected devices. Through voluntary certification testing, these standards have demonstrated that they provide interoperability to ensure that personal physiological data is incorporated into the record as structured actionable data.

Intel appreciates the opportunity to comment on the 2017 Interoperability Standards Advisory (Draft 2017 ISA). Your work to develop the ISA is essential to advancing health information interoperability. We make the following request to improve interoperability and to support the meaningful use stage 3 objective of incorporating patient generated health data into the health record.

Please add ITU H.810, H.811, H.812, and H.813 - a suite ITU standards for end-to-end, plug-and-play connectivity of personal connected health devices such as wireless blood pressure cuffs, weight scales, glucometers, and activity trackers that play a critical role in prevention and improved management of chronic condition – as an implementation specification for:

1) "III-A: “Push” Exchange: Interoperability Need: An unsolicited “push” of clinical health information to a known destination between individuals and systems" (page 60 of the Draft 2017 Interoperability Standards Advisory.)
2) "III-A: “Push” Exchange: Interoperability Need: Push Communication of Vital Signs from Medical Devices” (page 62 of the Draft 2017 Interoperability Standards Advisory.)

Together, ITU's H.810, H.811, H.812, and H.813 lay-out implementation specifications to support interoperability of personal health devices (blood press cuffs, weight scales, and glucometers) with clinical data systems and clinical decision making. These implementation specifications make it possible for clinicians to monitor their patients chronic conditions and bio-physical measures that indicate need for medication modifications, lifestyle changes, or a clinical intervention.

ITU H.810, H,811, H.812, and H.813 identify a range of open industry standards that will support the three key functions essential to interoperability of patient health data/physiologic measure collected from/by devices: a) Collection of data from a personal health device and subsequent transmission to a gateway or cloud intermediate system. This is the collection of a physiologic measurement (for example, a blood pressure reading) and sending it to a phone or personal computer (gateway device). b) Re-transmission of personal health data (physiologic measures) from a gateway device or system to a cloud or other data repository or intermediate system. This is the transmission of data from a cellphone to a cloud system for example. Data aggregation usually happens at this level. c) Re-transmission of data from a cloud or aggregation system to a Healthcare Information System (The HRN or more recently the "Healthcare Information System" interface). This is the final specification for data to be sent to a clinical or other healthcare information system (an EHR for instance) in a clinically useful way.

Additionally, we request that a footnote or asterisk note to explain that these ITU standards are Continua Design Guidelines, developed to provide a suite of open industry standards and specifications that enable several options to achieve end-to-end interoperability between personal medical devices and health information systems.

Finally, we ask that ONC add the following interoperability need to CREATE a NEW Interoperability Need - to support chronic condition management, care coordination and care management: Remote Patient Monitoring to Support Chronic Condition Management, Patient Education, and Patient Engagement and list ITU H.810, H.811, H.812, and H.813 as an implementation specification for remote patient monitoring interoperability.

Thank you for your consideration to include these standards into the ISA, a critical step towards integrating patient generated data into the clinical EHR.

Sincerely,

Alice B. Borrelli
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Intel Corporation
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